

CLAIMS

1. A process of establishing a standard specification for a medicinal plant material, the process comprising:

- 5 (i) preparing a test solution or test extract of a sample of the medicinal plant material which is known to possess the or each property required for the standard;
- (ii) submitting the said solution or extract to two or more analytical methods including (a) a combination of NMR spectroscopy and a
10 computer-based pattern recognition technique, and (b) one or more biological profiling techniques which provide a quantifiable measure of the biological effect of the plant and which include a proteomics analysis;
- (iii) obtaining results from the analytical methods used in step (ii); and
15 (iv) defining a standard specification for the said plant material on the basis of the results obtained in step (iii);

the process being conducted such that the NMR data reflect the totality of the compounds in the plant material which respond to the NMR technique being used.

20 2. A process of providing a sample of a medicinal plant material, which sample complies with a standard specification for that material which has been defined by the process of claim 1, the process comprising:

- (i') preparing a test solution or test extract of a candidate sample of the medicinal plant material;
- .25 (ii') submitting the said solution or extract to analysis by a combination of NMR spectroscopy and a computer-based pattern recognition technique;
- (iii') obtaining results from the analysis of step (ii'); and
- (iv) selecting the candidate sample if the results in step (iii') comply with

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the standard specification for the said material established in step (iv) of the process defined in claim 1;

the process being conducted such that the NMR data reflect the totality of the compounds in the plant material which respond to the NMR technique being used.

- 5 3. A process according to claim 2 wherein step (iv') is replaced by:
 - (iv'a) submitting the solution or extract prepared in step (i') to one or more biological profiling techniques which provide a quantifiable measure of the biological effect of the plant and which include a proteomics analysis;
 - 10 (iv'b) obtaining results from the or each technique used in step (iv'a); and
 - (iv'c) selecting the candidate sample if the results obtained in step (iii') defined in claim 2 and step (iv'b) above comply with the standard specification for the said material as established in step (iv) of the process defined in claim 1.

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4. A process according to any one of the preceding claims wherein the combination of NMR spectroscopy and a computer-based pattern recognition technique comprises:

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- (a) submitting the test solution or test extract to NMR spectroscopy and recording one or more NMR spectra; and
- (b) submitting the data obtained from the or each NMR spectrum to a multivariate analysis to generate one or more points on a score plot.

5. A process according to any one of the preceding claims wherein the 25 multivariate analysis is principal component analysis (PCA).

6. A process according to any one of the preceding claims wherein the proteomics analysis comprises:

- (i) providing a target cell selected according to the clinical indication in

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which the medicinal plant is active and incubating the target cells with the test solution or test extract; and

- (ii) subjecting the incubated cells to gel electrophoresis on a 2-D gel and observing the change in protein expression in the cells as a result of exposure to the said solution or extract.

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7. A process according to any one of the preceding claims which further comprises purifying the test solution or test extract of the sample of the medicinal plant material prior to carrying out the combination of NMR spectroscopy and computer-based pattern recognition.

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8. A process according to any one of the preceding claims wherein the medicinal plant material consists of, or is derived from, a whole plant, a part of a plant, a plant extract or a plant fraction.

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9. A process of providing a standard specification for a medicinal plant material, the process comprising:

- (i''') preparing a test solution or test extract of a sample of the said plant material which is known to possess the or each property desired for the standard;
- (ii''') submitting the test solution or test extract to NMR spectroscopy and recording one or more spectra;
- (iii''') submitting the data obtained from the or each said NMR spectrum to a multi-variate analysis to generate one or more points on a score plot; and
- (iv''') defining a sphere of acceptability around the points generated in step (iii''') as the, or as part of the, standard specification for the said plant material;

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the process being conducted such that the NMR data reflect the totality of the compounds in the plant material; which respond to the NMR technique being used.

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10. A process according to claim 9 wherein the multivariate analysis of step (iii") is performed using an unsupervised methodology.

11. A process of providing a sample of a medicinal plant material, which sample complies with a standard specification for that material which has been established

5 by the process of claim 9, the process comprising:

(i") preparing a test solution or test extract of a candidate sample of the said plant material;

(ii") submitting the test solution or test extract to NMR spectroscopy and recording one or more NMR spectra;

10 (iii") submitting the data obtained from the or each said NMR spectrum to a multivariate analysis to generate one or more points on a score plot; and

15 (iv") selecting the candidate sample as a sample which complies with the said standard specification only if the points generated on the score plot in step (iii") fall within a sphere of acceptability as defined in the standard specification established in step (iv") of the process defined in claim 9;

the process being conducted such that the NMR data reflect the totality of the compounds in the plant material which respond to the NMR technique
20 being used.

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~~A process according to any of the preceding claims wherein the plant material is derived from, or consists of, a mixture of two or more different plants.~~

25 13. A process according to claim 12 wherein the said mixture is a remedy from a system of traditional medicine where mixtures of plants or plant extracts are used.

14. A process according to claim 13 wherein the system of traditional medicine is Traditional Chinese Medicine or Ayurvedic Medicine.

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A process according to any one of the preceding claims wherein the sample of the medicinal plant material which possesses said the or each property desired for the standard is a sample of authenticated or audited plant material of which the provenance is known.

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